

Laparoscopic Gastric Bypass, Roux en-Y: technique and results in 300 cases with 3-48 month follow-up

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SUMMARY

Laparoscopic Gastric Bypass, Roux en-Y has been performed in over 300 procedures, with acceptable morbidity, and no mortality. Operating times approach those of the open operation. Weight loss averages 80% of excess body weight at one year, and is maintained through 48 months of post-operative follow-up. Concurrently, 96% of serious pre-operative co-morbidities were eliminated within 1 year of surgery. Diabetes mellitus is clinically reversed in 98% of afflicted patients. Laparoscopic Gastric Bypass is a safe and effective treatment for the serious health effects of clinically severe obesity.

INTRODUCTION

Laparoscopic Gastric Bypass, Roux en-Y is an advanced laparoscopic technique, comprised of proximal gastric transection, a gastrojejunostomy, and Roux en-Y enteroenterostomy. We previously described our technique and methods for this procedure¹, and have previously reported early results². We have now performed, through April 1998, 390 procedures, and have accumulated over 48 months follow-up experience, in some patients. This report describes technical advances, morbidity, weight loss results, and the reponse of co-morbidities, in our first 300 cases between October 1993 and December 1997, including 3 months to 48 months follow-up.

MATERIALS AND METHODS

Qualification for Surgery

Patients are considered for surgery based upon satisfaction of the minimal criteria for bariatric surgical treatment, as determined by the Consensus Development Panel of the National Institutes of Health³. In brief, these include those persons with body mass index greater than 40 kgm/m^2 , or greater than 35 kgm/m^2 when there are co-morbidities which are life-threatening, or detrimental to activities of daily living.

All of our patients continue to participate in a multistage educational and informational program, to accomplish full disclosure pre-operatively, and to engage them in compliance with bariatric management post-operatively. Patients attend an informational lecture or view a video, which addresses the etiology and risks of the disease of morbid obesity as well as the medical and surgical treatments. The various surgical options are outlined with their results and risks. Medical information and historical data are gathered by our nurse practitioner. Co-morbidities for each patient are diagnosed and graded for severity. Indications for bariatric surgery are thus established, consistent with recognized criteria developed by the Consensus Development Panel of the National Institutes of Health³ and the American Society for Bariatric Surgeons.

Diagnostic and consultative evaluations are tailored to the needs of the individual patient, based upon their pre-operative history. Concurrent with the final pre-operative history

and physical examination, the patient undertakes a true/false examination pertaining to the operation, it's risks, complications, and long-term sequelae. The importance of regular follow-up is repeatedly emphasized.

Study Group

This study includes the first three hundred consecutive patients undergoing Laparoscopic Gastric Bypass, Roux en-Y (LapGBP), between October 1993 and December 1997.

Patients whose operations were converted to open laparotomy are excluded. Patients have been followed prospectively for 3 months to 48 months, including current follow-up of 90% of patients, by office examination, or telephone evaluation.

Co-morbidities have been recorded and graded pre-operatively, and are re-evaluated post-operatively. Post-operative morbidity is recorded at the time of occurrence. There has been no mortality, in 390 cases.

Procedure

The laparoscopic procedure duplicates the anatomy and structure employed by the authors for open Gastric Bypass – no compromise of essential technique, to achieve limited access, is acceptable. The proximal gastric pouch is constructed with a volume of 15 cc. A 75 cm limb Roux en-Y is constructed from proximal jejunum, using an intracorporeal enteroenterostomy. A retrocolic, retrogastric gastroenterostomy is formed with a circular stapler, to provide a 12 mm stomal orifice. Accomplishment of the anastomosis in a 15 cc pouch requires peroral insertion of the stapler anvil, using a method adapted from the percutaneous gastrostomy procedure. The complete technique has been previously described.

We have used linear staplers from each of the major manufacturers. Each instrument requires variation in technique to achieve satisfactory results. We find that the 45mm ET45B⁴ instrument offers the most satisfactory quality, reliability and security of the currently available instruments.

Gastric transection with gastroenterostomy creates multiple intersecting staple lines. We choose to oversew the gastroenterostomy with a 2-0 polysorb suture, to enhance the

strength and security of the stapled closure.

Post-Operative Management

Patients undergo radiographic examination of the gastroenterostomy on the first post-operative day, using water-soluble contrast media, after which they begin a clear liquid diet immediately. Typically, patients are discharged on a clear liquid diet on the second post-operative day, and begin a soft solid diet one week later, emphasizing high protein and low fat intake.

Our comprehensive surgical weight management program emphasizes the importance of active patient involvement, using the new physiological tool created through surgery to achieve permanent dietary and behavioral change. This begins with educational sessions on nutrition, exercise and psychological adaptation, during the immediate post-operative period. Patients are given a comprehensive "Owner's Manual" regarding their surgery and the expected effects, and are required to maintain regular follow-up, at least bi-monthly, for the first year following surgery, during the rapid phase of weight loss. We recommend at least yearly follow-up thereafter.

RESULTS

Weight loss results with LapGBP in our series are comparable to those reported with open surgical technique^{5,6}. The average weight lost exceeds 50% of excess body weight (XSBW) within 6 months of surgery, and rises steadily to a mean of 80% XSBW at 12 months following surgery. Figure 1 demonstrates average percent of XSBW lost at various increments post-operatively. Table 1 shows the distribution of percentage of XSBW lost, versus time, for 24 to 48 months postoperative: in over 80% of patients, a loss of 60% or more of body weight persisted through 48 months postoperative.

Total numbers of co-morbidities were reduced overall by 96%, from 1163 pre-operatively, to 43 post-operatively. Post-operative co-morbidities, even when persisting, tended to be reduced in severity. Gastro Esophageal Reflux Disease was symptomatically eliminated in over 98% of patients afflicted pre-operatively. Clinical parameters of Diabetes Mellitus were eliminated in 98%, and reduced in the remaining patients. Sleep Apnea was clinically

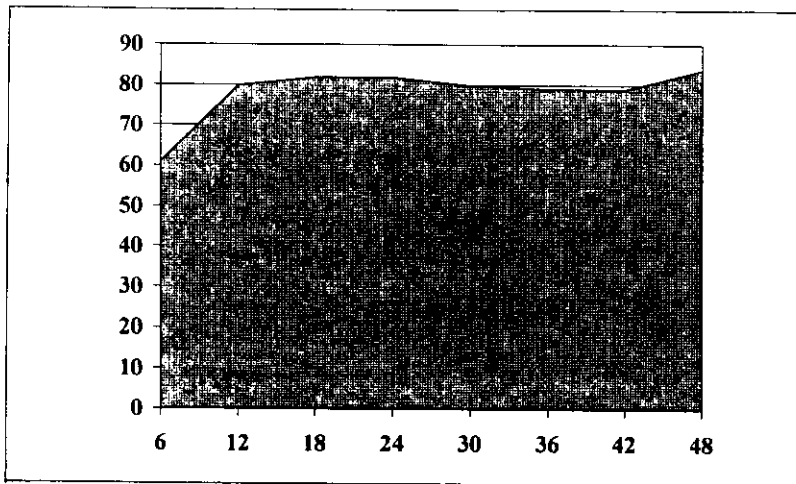


Figure 1. Laparoscopic gastric bypass:
% excess body weight lost per month post
operative for the first 300 cases

Table 1. Laparoscopic Gastric Bypass:
Distribution of % excess body weight lost in
first 300 cases

MONTHS POST OP	NO. OF PATIENT / CATEGORY				
	<50%	50-60%	61-75%	>75%	Total
24	3	5	10	44	62
30	6	5	6	29	46
36	4	2	4	19	29
42	1	2	4	10	17
48	0	1	2	5	8

Table 2. Laparoscopic gastric bypass:
Comparison of pre and post operative
co-morbidity in first 300 cases

CONDITION	PRE-OP	POST-OP
GERD	180	3
HYPERCHOLESTEROL	176	6
HYPERTRIGLYCERIDE	106	1
DIABETES	59	1
GLUCOSE INTOLERANCE	30	0
STRESS INCONTINENCE	134	4
SLEEP APNEA	150	2
HYPERTENSION	79	6
ARTHRITIS (symptomatic)	249	20
TOTAL	1163	43

resolved in 99% of afflicted patients. Of 79 hypertensive patients, 92% experienced clinical remission. Comparison of pre-operative and post-operative co-morbidities is shown in Table 2.

Patients affected with Diabetes, and its severity, are summarized in Table 3. Post-operative status for these patients is shown in Table 4. Only one of 59 Diabetics had elevated Hgb-A1C levels after the operation.

Table 3. Diabetics having laparoscopic gastric bypass: First 300 cases

<u>Pre-operative</u>	<u>Frequency</u>	
Chemical	34	17 had elevated HgbA1C
Oral agents	22	21 had elevated HgbA1C
Insulin	3	3 had elevated HgbA1C

n = 59 of 300 Patients who were diabetic pre-operative and another 30 patients were glucose intolerant

**Table 4. Laparoscopic gastric bypass:
Comparison of pre and post operative
Diabetes mellitus type II**

	PRE-OP	POST-OP
MEDICATION	25	0
ELEVATED HgbA1C	41	1

n= 59 OF 300 patients. Other than the one with high Hgb A1C, all others have normal fasting and 2-h post-prandial blood glucose.

There has been no mortality in our series. Complications from the entire series, some previously described, are included in this report for completeness. There have been no incisional hernias. Wound infections tend to be minor, and typically affect only one of the several trochar sites. Respiratory problems were minor and transient, despite the high-risk of this patient group. Intra-abdominal hemorrhage requiring reoperation occurred in three cases, and tended to be at the staple lines, not associated with anastomotic breakdown.

Table 5. Complications with laparoscopic gastric bypass: First 300 cases by type and frequency

<u>TYPE</u>	<u>FREQUENCY</u>
LEAK (Re-op: 2 open, 7 lap)	9
INFECTION (minor)	15
INFECTION (major)	2
RESPIRATORY (minor)	5
"STENOSIS"	3
SMALL BOWEL OBSTRUCTION (> 1 MO)	3
HEMORRHAGE (Re-op: 1 open, 3 lap)	4
PYELONEPHRITIS (Hx of stones)	1
STROKE	1

Pyelonephritis occurred in a patient with known stone disease, who had a history of multiple prior similar infections. The types and incidence of post-operative complications are shown in Table 5. All anastomotic leaks occurred at the gastrorrhaphy/gastroenterostomy site, and 7 of 9 were managed with laparoscopic re-operation.

Early in the series, operative times averaged approximately 4 hours. With refinement of techniques, and increased operating efficiency, operating time has approached that for the open gastric procedure. The average operating time for the last 20 cases is 120 minutes. Length of stay is no longer compiled – it has remained stable at 2.5 days during the first 150 operations.

CONCLUSIONS

Since the introduction of minimally invasive surgery just 7 years ago, a revolution in surgical techniques has occurred, as most surgical procedures have been adapted to limited access techniques. The demonstrated benefits of laparoscopic surgery include shorter hospital stay, earlier return to normal activity, superior cosmesis², and less pain. Additional dividends include less systemic stress and less immunologic stress⁷, reduced adhesion formation, and diminished ileus.

Bariatric surgical procedures are well-standardized, and very suitable to advanced laparoscopic methods. Exposure is often actually enhanced, in the very obese patient,

when compared to that achieved with laparotomy. We have found the limiting aspect of patient size to be the length of the instruments currently manufactured, not the actual size of the patient.

Successful long-term weight management is a function of intensive long-term patient support and follow-up, built upon a foundation of an effective surgical procedure.

Bariatric surgery should only be essayed in the context of a comprehensive program of weight management.

Technical success, especially in limited access surgery, depends heavily on the quality and reliability of the laparoscopic instrumentation. After progressive improvement in our anastomotic security and success for two years, we experienced an increased frequency of gastroenterostomy leakage between July and September 1997, in association with the use of a different linear stapler. After eliminating usage of this device, in September 1997, one leakage has occurred in the ensuing 93 procedures.

Though the stomach is usually regarded as thicker than the small intestine, we find the very proximal stomach pouch is not as thick as the main body of the stomach and that a 3.5 mm staple height – the same staple height we have used for over 10 years when performing the open procedure – recommended for intestinal anastomosis improves security and especially hemostasis. There are obviously multiple factors involved with successful formation of this anastomosis and we continue to evaluate our methods.

At this time, we perform over 50% of operations using this minimally invasive technique. The operative times have decreased toward 110 minutes – only slightly longer than the equivalent open procedure. Average length of hospital stay has remained consistent at 2.6 days. As with the open procedure^{8,9,10}, reduction of co-morbidity is dramatic, with over 96% of the associated health risks being eliminated – the critical indication for performance of bariatric surgery.

We have shown in this report that Laparoscopic Gastric Bypass, Roux en-Y can be accomplished with minimal mortality, and acceptable morbidity, and with reasonable operating times. When performed in the setting of a comprehensive surgical weight reduction program, weight loss results are very gratifying, and over 95% of all co-morbidities are eliminated.

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